UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA

Pacira Pharmaceuticals, Inc., Plaintiff v. Research Development Foundation, Defendant	Case No. 2:21-cv-02241-CDS-NJK **Order Resolving RDF's Motions in Limine to Exclude Plaintiff's Expert Witnesses** [ECF No. 224, 250, 225, 251]

Plaintiff Pacira Pharmaceuticals, Inc. sues defendant Research Development Foundation ("RDF") in this declaratory-judgment action arising out of a long-standing assignment agreements between the parties. RDF filed two motions in limine seeking to exclude parts of the testimony of Pacira's expert witnesses Dr. Thomas and Dr. Ho. RDF Motion re: Thomas, ECF No. 224 (sealed); ECF No. 250 (unsealed); RDF Motion re: Ho, ECF No. 225 (sealed); ECF No. 251 (unsealed). Pacira opposes the motions. Opp'n to Thomas MTE, ECF No. 263 (sealed); Opp'n to Ho MTE, ECF No. 262 (sealed).[1] RDF filed replies to Pacira's oppositions. RDF Reply re: Thomas, ECF No. 285; RDF First Reply re: Ho, ECF No. 282; RDF Second Reply re: Ho, ECF No. 299.[2] For the reasons described herein, I deny RDF's motions in limine to exclude the testimony of Dr. Thomas and Dr. Ho.

I. Legal standard

The court incorporates the standard set forth in the order resolving Pacira's motions in limine to exclude, ECF No. 307.

[1] RDF also filed a sealed (ECF No. 226) and an unsealed (ECF No. 252) appendix of exhibits in support of its motion to exclude parts of Dr. Ho's testimony.

[2] The only difference between RDF's two replies regarding Ho is that a single line was redacted in the first (ECF No. 282 at 5) and unredacted in the second (ECF No. 299 at 5). Because the latter one is more complete, I will be referring to it when discussing RDF's reply regarding exclusion of parts of Ho's testimony.

II. Discussion

As background, the parties do not dispute that "whether Pacira's New Patents 'relate to the Assigned Proprietary Property' under Section 3.8 of the 1994 Agreement" is an issue to be decided at trial. ECF No. 232 (citing ECF No. 178 at 6); ECF No. 264 at 4 (citing Summ. J. Order, ECF No. 152 at 17–18). Pacira also asserts that their claim for declaratory judgment of unenforceability, specifically identifying unenforceability on the grounds of unconscionability and public policy, together with RDF's competing request for declaratory relief on the same, is also a live issue for trial. ECF No. 232 at 6. I agree.[3] With that I mind, I resolve the two motions in limine to exclude as follows:

A. RDF's motion in limine to exclude parts of the testimony of Dr. Thomas

In his expert report, Dr. Chrisanthus Thomas discusses differences between the 200L and 45L processes, the amount of effort Pacira put into developing the 200L process, and differences in the properties of 200L and 45L EXPAREL®, among other things. *See* Thomas rep., ECF No. 250-2. RDF seeks large parts of Thomas's expert report excluded because his analysis of the differences between the 45L and 200L processes, and Pacira's efforts in the 200L process development, is irrelevant. ECF No. 250 at 6–8. Additionally, it argues that his opinions comparing data for the properties of the 200L and 45L processes for making EXPAREL® are unreliable. *Id.* at 8–11.

1. Thomas's analysis of the differences between Pacira's 45L and 200L processes

RDF first argues that Thomas's opinions regarding the differences between the 45L and 200L processes are irrelevant. *Id.* at 6–7. It contends that his report focuses only on the

[3] Despite RDF's new assertions that the unconscionability issue is no longer live, it is. *See* Pretrial Order, ECF No. 170 at 17 (asserting that "[w]hether any payment-related terms or provisions of the parties' Agreements are unconscionable, against public policy, or otherwise void or unenforceable" is a contested issue of law). RDF itself previously argues that this issue was contested, making its new assertions all the more puzzling. *See* RDF's Answer, ECF No. 18 at 27 (seeking a declaration that "Agreements and the terms therein are valid, enforceable, and not unconscionable or in violation of public policy.").

differences between the processes, not the '495 and the '838 patents or any other patents at issue, thus proving unhelpful to understanding whether '495 or the other New Patents[4] relate to '838. *Id.* In response, Pacira argues that his testimony is relevant to Pacira's unenforceability claim because he discusses all the manners in which Pacira innovated to create the 200L process. ECF No. 10–11. Pacira also argues that Thomas's difference in processes testimony is independently relevant as rebuttal evidence if RDF "improperly" introduces argument about evidence extrinsic to the patents suggesting the processes are similar. *Id.* at 11–12. In its reply, RDF contends that its objection is to Thomas's testimony about differences in the 45L and 200L processes that were not disclosed in the New Patents, which it argues are outside the scope of the patents and serve no useful function in comparing the patents. ECF No. 285 at 5–6.

I find that Thomas's comparison of the 45L and 200L processes is relevant to the unenforceability question. Under Rule 401, evidence is relevant if it has "any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." Fed. R. Evid. 401. Depending on the court's decision regarding whether the patents are "related to" each other, the difference in the processes, and thus the amount of innovation Pacira undertook in developing the 200L process, could be a "fact that is of consequence" to the question of whether it would be unconscionable to require Pacira to pay a royalty to RDF under the 200L process. Therefore, RDF's motion to exclude Thomas's testimony about the differences in the 200L and 45L processes is denied without prejudice.

2. Thomas's opinions about Pacira's efforts to develop its 200L process

In a related argument, RDF contends that Thomas's opinions are the result of a confidential, internal process at Pacira and serve no function in evaluating the relatedness between the '495 and '838 patents. ECF No. 250 at 7–8. I disagree for the same reasons as I

[4] The "New Patents" are a series of patents issued to Pacira that include U.S. Patent Nos. 11,033,495; 11,179,336; 11,278,494; 11304,904; 11,311,486; 11,357,727; 11,426,838; and 11,452,691. *See* proposed joint pretrial order, ECF No. 170 at 2 n.2.

decline to exclude Thomas's testimony about the differences in processes. These opinions are also potentially relevant to the unenforceability question because the amount of effort Pacira put into developing the 200L process helps answer whether enforcement of the Agreements would be unconscionable. Thus RDF's motion to exclude Thomas's testimony about Pacira's efforts to develop the 200L processes is denied without prejudice.

3. Reliability of Thomas's opinions

According to RDF, based on argument in another case involving the '495 patent, the '495 patent included incomplete and inaccurate data. ECF No. 250 at 8–10 (citing *Pacira Pharms., Inc. v. eVenus Pharms. Labs., Inc.*, Civil Action Nos. 2:21-cv-19829-MCA-JRA, 2:22-cv-00718-MCA-JRA (D.N.J.) [hereinafter *eVenus* litigation]). It argues that because Thomas did not evaluate the batch data and relied only on the data included in the '495 patent, his opinions are unreliable. *Id.* It separately argues that his opinions are based on unreliable methodology because he conducted "no independent analysis," merely recited the data in '495, and did not use "scientifically reasonable criteria" in his comparisons. *Id.* at 10–11.

In response, Pacira advances a number of arguments, including that RDF's own purported expert Dr. Michniak-Kohn also did not rely on any batch data, that RDF mischaracterizes what transpired in the *eVenus* litigation, that Thomas makes a total of two references to the '495 data, that the "relate to" question is a patent rights issue and so Thomas should be neither expected nor required to pull from outside data, and that any objections RDF has about lack of reliance on batch data should go to the weight of his opinions, to their admissibility. ECF No. 263 at 12–14. Pacira incorporated by reference its similar arguments regarding RDF's objections to Dr. Ho's analysis of the '495 data in its response to RDF's motion to exclude portions of Ho's testimony. *Id.* at 8 n.5 (incorporating by reference ECF No. 262 at 18–21). Pacira also argues that RDF's objections to Thomas's methodology are disagreements about his data analysis and conclusions, which are not reasons for exclusion. *Id.* at 14–15.

I see no reason to exclude Thomas's testimony based on the reliability of his data or his methodology at this time. Reliability requires the court to assess whether an expert's testimony has a "reliable basis in the knowledge and experience of the relevant discipline." *Kumho Tire Co. v Carmichael*, 526 U.S. 137, 149 (1999) (citation and alterations omitted). The "evidentiary reliability [is] based upon scientific validity." *Daubert v. Merrell Down Pharms., Inc.*, 509 U.S. 579, 590 n.9 (1993). The relevant concern is "not [with] the correctness of the expert's conclusions but the soundness of his methodology." *Primiano v. Cook*, 598 F.3d 558, 564 (9th Cir. 2010) (citations and quotations omitted). The court must "act as a 'gatekeeper' to exclude junk science that does not meet Federal Rule of Evidence 702's reliability standards." *Ellis v. Costco Wholesale Corp.*, 657 F.3d 970, 982 (9th Cir. 2011). There is nothing in RDF's motion that suggests an unreliability so fatal as to necessitate Thomas's testimony's exclusion. Whether he relied on the data in '495 without considering necessary additional data, or his conclusions about the data itself, are areas that can be addressed in cross-examination. Accordingly, RDF's motion to exclude Thomas's testimony based on the alleged unreliability of his data or methodology is denied without prejudice.

B. RDF's motion in limine to exclude parts of the testimony of Dr. Ho

RDF objects to large parts of Dr. Rodney Ho's report, arguing the court should exclude his comparison of "Original Patented Technology" and "New Patented Technology" because it is irrelevant, that his comparison of data for certain properties of the 45L and 200L processes because is unreliable, and that his rebuttal of Dr. Michniak-Kohn's conclusions is improper rebuttal testimony. ECF No. 251 at 7–16.

1. Relevance of Ho's comparison of "Original" and "New" patented technology

RDF first argues that Ho's comparison between "Original Patented Technology" (the 45L process) and the "New Patented Technology" (the 200L process) is irrelevant because the processes do not neatly align with the '838 (or '572) patent and '495 patent, respectively, and the

only remaining issue is whether '495 "relates to" the assigned proprietary property, which includes '838. *Id.* at 7–8. RDF also argues that Ho did not address the scope or content of the '838 patent, his analysis of confidential manufacturing processes is irrelevant for the issue of public patents, and that his reliance on the requirement to file a supplemental approval with the FDA for the 200L process and the U.S. Patent Office's granting of the '495 patent is also irrelevant to the relatedness question. *Id.* at 8–10. Like its response to the motion in limine to exclude Dr. Thomas, Pacira argues that Ho's opinions are relevant to the question of unenforceability, because his comparison of the processes could assist the court in understanding whether enforcement of the Agreements for the '495 patent would be unconscionable. ECF No. 262 at 13–14. Pacira makes a laundry list of other arguments in response to RDF's relevance challenges, but most can be addressed under the umbrella of RDF's failure to adequately consider evidence relevant to the unenforceability argument in its motion. *Id.* at 14–18.

I find that Ho's opinions comparing the EXPAREL® processes are relevant to the question of unenforceability. As to RDF's argument that Ho should not be permitted to testify about the requirement to file a supplemental approval with the FDA for the 200L process, I find that this falls under the same umbrella: it offers relevant information about the differences between the processes that may aid the court in making a decision as to Pacira's unenforceability argument. His opinions relating to the confidential Pacira manufacturing processes will likewise be helpful. Further, Ho's opinion that the U.S. Patent Office's granting of the '495 patent suggests that the 200L process is "novel," is not a legal conclusion that bears on the applicable law in this case and could be relevant to unenforceability and even the "related to" question. *See GemCap Lending, LLC v. Quarles & Brady, LLP*, 269 F. Supp. 3d 1007, 1028 (C.D. Cal. 2017) ("An expert witness cannot render an opinion as to a legal conclusion, as 'instructing the jury ***as to the applicable law*** is the distinct and exclusive province of the court.'" (quoting *Nationwide Transp. Fin. v. Cass Info. Sys., Inc.*, 523 F.3d 1051, 1058 (9th Cir. 2008)) (emphasis added)).

Therefore, RDF's motion to exclude Ho's testimony based on lack of relevance is denied without prejudice.

2. Reliability of Ho's data and methodology

RDF argues that Ho's opinions rely on deficient data based on representations in the *eVenus* litigation. As discussed above with Thomas, Ho's apparent failure to consider outside data is an issue for cross-examination, not grounds for exclusion. RDF also argues that Ho conducted "no independent analysis" but merely recited what is in the '495 patent tables when comparing the 200L and 45L processes, which it states has fundamental problems. ECF No. 251 at 12–13; ECF No. 299 at 10–12. As with the allegedly deficient data, RDF's objections to Ho's testimony, which includes argument that he relied on missing information—for example, comparing 200L and 45L EXPAREL® at one, two, and three months, but there is no data for the reference samples on the first month—are the exact sort of evidentiary disputes for which cross-examination is designed. Thus RDF's motion to exclude Ho's testimony based on unreliability is denied without prejudice.

3. Whether Ho offers improper rebuttal opinions

Ho produced a second report offering a rebuttal of both "Amendment Technical Scope Analysis" and "Technology Area Analysis" portions of RDF's purported expert Dr. Michniak-Kohn's report. Ho rebuttal rep., ECF No. 252-3. As to his rebuttal of her Amendment Technical Scope Analysis," RDF argues that Ho's testimony does not actually challenge the opinions of Michniak-Kohn's report but instead introduces a "temporal limitation" argument that is irrelevant to the issues for trial. ECF No. 251 at 14–15 (citing *Downs v. River City Grp., LLC*, 2014 WL 814303, at *5 (D. Nev. Feb. 28, 2014) (Rebuttal experts "must restrict their testimony to attacking the theories offered by the adversary's experts.")). It also contends that his temporal limitation theory is based on § 1.4 of the 2004 Amendment and serves no useful function in in determining whether '495 is related to '838 or '572 under § 3.8 of the 1994 Agreement. *Id.* at 15. As to his rebuttal of her "Technology Area Analysis," RDF argues that he misinterprets her opinion

and therefore does not contradict it, incorrectly assuming her "Technology Area Analysis" relies on her 'Amendment Technical Scope Analysis," when in reality they are entirely separate. *Id.* at 15–16.

In response, Pacira argues that RDF relies on a flawed premise, assuming that a rebuttal must rely only upon the same evidence as the testimony it rebuts. ECF No. 262 at 23–24 (citing *Laflamme v. Safeway, Inc.*, 2010 WL 3522378, at *3 (D. Nev. Sept. 2, 2010) ("[O]pining on methods and facts [defendant's] expert[] did not consider are precisely the type of rebuttal testimony the court would expect."")). It further argues that the RDF initiated the argument that "opinions regarding Section 1.4 of the 2004 Amendment are relevant to Section 3.8 of the 1994 Agreement because they are supposedly a "data point" for the "degree of relatedness" between the '838 Patent and the '495 Patent[,]" and Ho's rebuttal naturally responds to this. *Id.* at 24. It separately argues that his "Technology Area Analysis" is relevant because it directly contests Michniak-Kohn's assertion that "the '495 Patent overlaps with the technology of the '572 Patent[.]" *Id.* at 24–25 (quoting Michniak-Kohn rep., ECF No. 232-4).

As to RDF's initial argument, I agree with Pacira that Ho was not wrong in considering evidence not directly discussed in Michniak-Kohn's report. It would be nonsensical for our system to allow for rebuttal witnesses but prevent them from making one of the key rebuttal arguments: that the expert they are seeking to rebut has neglected to consider vital information. Further, because I have already found that Michniak-Kohn's report's discussion of § 1.4 is not to be excluded, I do not find grounds to exclude Ho's discussion of the same. *See* Order resolving Pacira's motions in limine to exclude defendant's expert witnesses. ECF No. 307. Finally, RDF's objections to Ho's rebuttal of Michniak-Kohn's "Technology Area Analysis" are once again better suited for cross-examination. An expert's supposed mistake does not automatically establish grounds for exclusion. *See, e.g.*, *United States v. Rounds*, 2015 U.S. Dist. LEXIS 145540, *6 (W.D.N.Y. Oct. 26, 2015) ("[Defendant] will, of course, have a full and fair opportunity for cross-examination, which, rather than preclusion, is the proper mode for exposing any weakness in

the expert's opinion.") I note, however, that while serving as a rebuttal witness, Ho may only testify in response to Michniak-Kohn's testimony; his rebuttal cannot address—just as Michniak-Kohn may not testify about—the rejected "field of technology" theory. RDF's motion to exclude Ho's rebuttal testimony is denied without prejudice.

III. Conclusion

It is therefore ordered that RDF's motions in limine **[ECF No. 224/ECF No. 250; and ECF No. 225/ECF No. 251] are DENIED** as set forth in this order.

Dated: September 18, 2024

Cristina D. Silva
United States District Judge